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EXAMINER	
MASKELL, MICHAEL P	

ART UNIT	PAPER NUMBER
2881	

NOTIFICATION DATE	DELIVERY MODE
09/05/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/556,485	MORITZ ET AL.	
	Examiner	Art Unit	
	MICHAEL MASKELL	2881	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28 and 30-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28 and 30-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/18/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/18/2008 has been entered.

Information Disclosure Statement

2. The information disclosure statement filed 08/18/2008 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

The applicant's amendment has removed the indefinite language from claim 42, and the previous rejection of this claim for indefiniteness is withdrawn.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 8, 38, 39 and 40 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention. In the replies filed 04/21/2008 and 08/18/2008, the applicant challenged the examiner's stated interpretation of the term "roughly" used in the above claims (the examiner had given the term an interpretation to include up to a 50% deviation from the given value). The applicant has not, however, provided any guidance as to what interpretation of this term should be used in the present application. The applicant has simply rejected the examiner's interpretation and left the term undefined. Claims 8, 38, 39 and 40 therefore are left drawing an unclear line between what is and is not considered the applicant's invention, and so they fail to distinctly claim the subject matter which the applicant regards as his invention.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 6, 9, 15 and 16 rejected under 35 U.S.C. 102(b) as being anticipated by Tanner, et al (U.S. Patent Application Publication 2003/0003474 A1).

Regarding claim 1, Tanner discloses a sample holder for application in MALDI mass spectrometry (Tanner's invention is a substrate for performing multiple assays of biological materials, and MALDI mass spectrometry is frequently used for assaying biological materials), comprising: a substrate (paragraph 0009); a porous film present on the substrate and comprising metal oxide particles (paragraphs 0009 and 0011).

Regarding claim 2, Tanner discloses the sample holder according to claim 1,

characterized in that the metal oxide particles are selected from the group including titanium dioxide, zirconium dioxide, niobium oxide, aluminum titanium oxide, tungsten zirconium oxide, hafnium dioxides, tungsten oxide, tin dioxide, lead oxide, lead dioxide, germanium dioxide, and gallium oxide (paragraph 0011).

Regarding claim 6, Tanner discloses the sample holder according to claim 1, characterized in that the film has a thickness in the range from 0.1 micrometers to 10 micrometers (paragraph 0012).

Regarding claim 9, Tanner discloses the sample holder according to claim 1, characterized in that the substrate consists of glass or coated glass (paragraph 0033).

Regarding claims 15 and 16, Tanner discloses the sample holder according to claim 1, furthermore comprising: one or several samples to be analyzed, which are applied on the film and which is or are presumed to contain one or several substances of interest, selected from the group including nucleic acids and proteins (paragraph 0052).

3. Claims 19, 20 and 24 rejected under 35 U.S.C. 102(b) as being anticipated by Barrow, et al (U.S. Patent 5,585,136).

Regarding claims 19 and 33-40, Barrow discloses a method of preparing a substrate and a porous film applied on the substrate and including metal oxide particles, which method comprises the following steps of operation: preparing a sol from a metal oxide and inducing gel formation, for example by restriction and/or thermal treatment (column 2, line 65-column 3, line 10; Barrow refers to forming the sol gel with ceramic

powder, and the definition of "ceramic" according to *The American Heritage® Science Dictionary.* Retrieved December 11, 2007, from Dictionary.com website: http://dictionary.reference.com/browse/ceramic is a material "made typically of metallic elements combined with oxygen," hence a metal oxide); applying the gel on a substrate, drying and subsequent tempering at 200-600 degrees C, preferably 300 to 450 degrees C, most preferably at roughly 400 degrees C, for a period of 30 minutes to 180 minutes, preferably 30 minutes to 60 minutes, most preferably for roughly 45 minutes (column 4, lines 35-49).

Regarding claim 20, Barrow discloses a method according to claim 19, characterized in that the metal oxide particles are selected from the group including titanium dioxide, zirconium dioxide, niobium oxide, aluminum titanium oxide, tungsten zirconium oxide, hafnium dioxides, tungsten oxide, tin dioxide, lead oxide, lead dioxide, germanium dioxide, and gallium oxide (Table 1 lists some of the ceramic powders from which the oxide compounds are formed (column 4, lines 45-50); among these powders are for example Titanium and Zirconium, which would naturally and inherently form titanium dioxide and zirconium oxide, respectively, when oxidized as taught by Barrow).

Regarding claim 24, this claim is simply the product of the process of claim 19, and is thus anticipated for the same reasons.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 3-5 rejected under 35 U.S.C. 103(a) as being unpatentable over Tanner in view of Ellson, et al (U.S. Patent Application Publication 2002/0171037 A1).

6. Tanner teaches the sample holder of claim 1, but fails to teach the film having a mean pore size of <50 nm, or from 1 nm to 25 nm, or from 1 nm to 10 nm. However, Ellson teaches a porous substrate for holding a MALDI sample with an average pore size of about 10 nm (paragraph 0048). Because these teachings are analogous art (Tanner is directed towards a substrate for multiple biological assays, and Ellson is directed towards analyzing a surface containing a biological sample), one of ordinary skill in the art would be familiar with both teachings; therefore, Ellson's teachings show that a mean pore size of about 10 nm is within the technical grasp of one of ordinary skill in the art. It has been found that "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." (*KSR International Co. v. Teleflex Inc.,* 550 U.S.___, 82 USPQ2d 1385 (2007)). It would therefore have been obvious to one of ordinary skill in the art at the time the invention was made to provide a mean pore size of about 10 nm. Doing so is a known option within the technical grasp of one of ordinary skill, and as taught by Ellson would lead to anticipated success.

7. Claims 7 and 8 rejected under 35 U.S.C. 103(a) as being unpatentable over Tanner in view of Barrow.

Tanner discloses the sample holder of claim 6, but fails to teach specifically

wherein the film has a thickness of roughly 3 micrometers; however, Barrow discloses that the production of thin films containing metal oxide particles with a thickness of 3 micrometers was within the level of ordinary skill in the art at the time of the invention (column 1, lines 40-45).

It has been held that "When a work is available in one field, design incentives and other market forces can prompt variations of it, either in the same field or in another. If a person of ordinary skill in the art can implement a predictable variation, and would see the benefit of doing so, §103 likely bars its patentability." (*KSR Intl. Co. v. Teleflex, Inc.* 550 U.S.___ 82 USPQ2d 1385 (2007)) Since methods of producing thin films containing metal oxide particles were available to one of ordinary skill in the art at the time the invention was made, the variation of the thickness of the film in Tanner's sample holder to roughly 3 micrometers would have been a predictably created one when prompted by design incentives and other market forces. It would therefore have been obvious to one of ordinary skill in the art at the time the invention was made to use a film of roughly 3 micrometers thickness in Tanner's sample holder.

8. Claims 10-13 rejected under 35 U.S.C. 103(a) as being unpatentable over Tanner in view of Wood, et al (U.S. Patent Application Publication 2004/0094705 A1). Tanner teaches the sample holder according to claim 9, but fails to teach that the glass is a conductive glass or a glass with a conductive coating, or coated with indium tin oxide (ITO). However, Wood teaches a sample holder for MALDI mass spectrometry that may be advantageously used with one or more coatings, one of which is ITO (paragraphs 0095 and 0096).

Tanner and Wood's teachings are analogous art because Tanner teaches a substrate for biological assays, and Wood teaches a substrate for MALDI mass spectrometry, which is a kind of biological assay; further, Wood teaches a metal oxide coating similar to that taught by Tanner, and teaches that multiple coatings of different types can be used in combination (such as an ITO coating on the glass substrate, followed by the metal oxide film taught by Tanner). Finally, Wood teaches that an ITO coating is advantageous because it provides enhanced desorption, which is desirable for MALDI. It would therefore have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings, resulting in the sample holder of claims 10 and 11. Doing so would improve desorption of the sample from the MALDI sample holder.

In regards to claim 12, Tanner discloses all limitations except for “a MALDI matrix overlying the porous film.” Wood remedies this deficiency by providing a matrix over his own disclosed porous film (paragraph 0011). Doing this in Tanner's apparatus would have been obvious to one of ordinary skill in the art because it is a standard way of using a microassay sample holder.

In regards to claim 13, Wood further teaches the use of alpha cyano-4-hydroxy-cinnamic acid as a MALDI matrix. Because this is a common matrix for use in MALDI applications, using it would have been obvious to one of ordinary skill in the art.

9. Claim 14 rejected under 35 U.S.C. 103(a) as being unpatentable over Tanner in view of Mayer-Posner, et al (U.S. Patent 6,414,306).

10. Tanner teaches the sample holder according to claim 1, but fails to teach that the film applied on the substrate is present only at defined areas specifically envisaged to this end, covering same, whereas other ranges therebetween are left free of film. However, Mayer-Posner teaches a MALDI mass spectrometry sample carrier plate where the film applied on the substrate is present only at defined areas specifically envisaged to this end, covering same, whereas other ranges therebetween are left free of film (column 8, line 63-column 9, line 8).

The teachings are analagous art because Tanner teaches a substrate for performing biological assays and Mayer-Posner teaches MALDI mass spectrometry, which is a kind of biological assay. Further, Mayer-Posner teaches a motivation for the claimed film arrangement, in that samples can be separated yet closely spaced to increase throughput of analysis. It would therefore have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings to provide the sample holder according to claim 14; doing so would gain the throughput advantage taught by Mayer-Posner.

11. Claims 17, 18, 26-28 and 31rejected under 35 U.S.C. 103(a) as being unpatentable over Tanner in view of Kuroda, et al (U.S. Patent Application Publication 2005/0170525 A1) and in view of Mayer-Posner.

Regarding claims 17 and 31, Tanner teaches the sample holder according to claim 16, but fails to teach that the proteins are phosphorylated and/or sulphated. However, Kuroda teaches the analysis of phosphorylated and/or sulphated proteins/peptides using MALDI-MS and a similar metal oxide coating (paragraph 0412).

Tanner and Kuroda's teachings are analogous art because Tanner's teachings are directed towards a substrate for biological assays, and Kuroda's teachings are directed towards methods of performing biological assays.

Tanner in view of Kuroda makes a strong case for prima facie obviousness for these reasons; however Mayer-Posner is offered to provide further evidence of obviousness. Mayer-Posner teaches a MALDI mass spectrometry sample plate comprising a thin, porous layer containing metal oxide (column 4 lines 64-67). This provides a suggestion in the prior art to combine the substrate coated with a porous metal oxide layer taught by Tanner with the MALDI analysis of phosphorylated peptides taught by Kuroda, by demonstrating that a similar plate has been successfully used in MALDI mass spectrometry. It would therefore have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings, resulting in the method of claims 17 and 31. Doing so is taught to be particularly favorable by Mayer-Posner.

Regarding claims 18 and 32, Tanner teaches the sample holder according to claim 1 (this claim is being treated as though "the present invention" refers to claim 1, see 112 indefiniteness rejection above), but fails to teach providing a sample which is presumed to contain phosphorylated/sulphated biopolymers, specifically peptides/proteins, alone or in combination with other biopolymers, specifically peptides/proteins, and applying the sample on the sample holder, and performing MALDI mass spectrometry. However, Kuroda teaches providing a sample which contains phosphorylated peptides, applying the sample on a sample holder, and

performing MALDI mass spectrometry (paragraph 0412).

Tanner and Kuroda's teachings are analogous art because Tanner's teachings are directed towards a substrate for biological assays, and Kuroda's teachings are directed towards methods of performing biological assays. Tanner in view of Kuroda makes a strong case for prima facie obviousness for these reasons; however Mayer-Posner is offered to provide further evidence of obviousness. Mayer-Posner teaches a MALDI mass spectrometry sample plate comprising a thin, porous layer containing metal oxide (column 4 lines 64-67). This provides a suggestion in the prior art to combine the substrate coated with a porous metal oxide layer taught by Tanner with the MALDI analysis of phosphorylated peptides taught by Kuroda, by demonstrating that a similar plate has been successfully used in MALDI mass spectrometry. It would therefore have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings, resulting in the method of claims 18 and 32. Doing so is taught to be particularly favorable by Mayer-Posner.

Regarding claims 26, 27 and 41, as explained in regards to claim 18 above, Tanner teaches the sample holder according to claim 1, but fails to teach the selective detection of phosphorylated/sulfated biopolymers, specifically peptides/proteins, and the detection being performed by means of MALDI mass spectrometry; however, for the same reasons given in regards to claim 18, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Tanner with Kuroda in view of Mayer-Posner to apply such a sample and detect it with MALDI mass spectrometry.

12. Claims 21-23 and 25 rejected under 35 U.S.C. 103(a) as being unpatentable over Barrow in view Tanner in view of Ellson. Barrow teaches the method of claim 19 and the sample holder of claim 24, but fails to teach the film having a mean pore size of <50 nm, or from 1 nm to 25 nm, or from 1 nm to 10 nm. Tanner teaches a substrate similar to that produced by Barrow, and teaches its application to biological assays. Ellson teaches a porous substrate for holding a MALDI sample with an average pore size of about 10 nm (paragraph 0048).

Because these teachings are analogous art (Barrow is directed towards the method of preparing a substrate, Tanner is directed towards using a similar substrate for multiple biological assays, thus providing the analogous link between Barrow and Ellson, and Ellson is directed towards analyzing a surface containing a biological sample), one of ordinary skill in the art would be familiar with the teachings; therefore, Ellson's teachings show that a mean pore size of about 10 nm is within the technical grasp of one of ordinary skill in the art.

It has been found that "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." (*KSR International Co. v. Teleflex Inc.,* 550 U.S.___, 82 USPQ2d 1385 (2007)). It would therefore have been obvious to one of ordinary skill in the art at the time the invention was made to provide a mean pore size of about 10 nm. Doing so is a known option within the technical grasp of one of ordinary skill, and as taught by Ellson would lead to anticipated success.

13. Claims 30 and 42 and 43 rejected under 35 U.S.C. 103(a) as being unpatentable over Barrow in view of Kuroda and Mayer-Posner. Barrow teaches the sample holder according to claim 24 (which satisfies the limitations of claim 1 as well), but fails to teach applying a sample on the metal oxide film of the sample holder, which is presumed to contain phosphorylated/sulphated biopolymers, specifically peptides/proteins; washing the metal oxide film in one or several washing operations; applying a phosphate-containing medium onto the metal oxide film of the sample holder; and applying a MALDI matrix onto the metal oxide film of the sample holder. However, Kuroda teaches applying a sample onto the metal oxide film of the sample holder (paragraph 0409 describes the metal oxide film), which is presumed to contain phosphorylated/sulphated biopolymers, specifically peptides/proteins (paragraph 0412 describes the application and the composition of the sample); washing the metal oxide film in one or several washing operations (paragraph 0411); applying a phosphate-containing medium onto the metal oxide film of the sample holder (paragraph 0412); and applying a MALDI matrix onto the metal oxide film of the sample holder (paragraph 0142 describes the use of a MALDI plate to detect the peptide via MS; MALDI inherently requires the application of a MALDI matrix, hence the name “Matrix Assisted Laser Desorption Ionization”).

These teachings are analogous art because Kuroda teaches the use of a porous metal oxide coating on the MALDI sample substrate, while Barrow teaches the details of forming such a metal oxide coating. Barrow in view of Kuroda makes a strong case for prima facie obviousness for these reasons; however, Mayer-Posner is offered to provide further evidence of obviousness.

Mayer-Posner teaches a MALDI mass spectrometry sample plate comprising a thin, porous layer containing metal oxide (column 4 lines 64-67). This provides a suggestion in the prior art to combine the method of forming a substrate coated with a porous metal oxide layer taught by Barrow with the MALDI analysis of phosphorylated peptides taught by Kuroda, by demonstrating that a similar plate has been successfully used in MALDI mass spectrometry. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings, resulting in the method of claim 30. Doing so is a known application of a substrate analogous to the product produced by Barrow's process, so the combination is an application of known elements together with no change in their individual function.

Response to Arguments

14. Applicant's arguments filed 08/18/2008 have been fully considered but they are not persuasive.

15. The applicant's argument regarding the interpretation of "roughly" as it is applied to the rejection of claims 7 and 8 is moot in view of the new grounds of rejection of claims 7 and 8 as obvious over Tanner in view of Barrow.

16. The applicant's argument regarding the comparison of the instant substrate with the Tanner substrate (applicant's reply, page 13) is not persuasive because it relies on limitations that are not present in the claims. The applicant states that "the specification indicates that the instant substrate is only something that is a carrier to hold the inventive porous film. As such, the substrate in the instant claims is not able to bind an analyte." If the substrate in the instant claims is to be limited to those substrates that

are not able to bind an analyte, such limitation must be present in the claim. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

17. In regards to claim 19, the applicant states that claim 19 has been amended to distinguish the instant claims from Barrow (applicant's reply, page 14); however, in the current claims listing, the only amendment appearing to claim 19 is the removal of the indefinite "for example" and "and/or" language. This does not appear to distinguish over Barrow, and if the applicant believes it does, the applicant must explain why.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL MASKELL whose telephone number is (571)270-3210. The examiner can normally be reached on Monday-Friday 8AM-5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Kim can be reached on 571/272-2293. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Maskell/
Examiner, Art Unit 2881
28 August 2008

/ROBERT KIM/
Supervisory Patent Examiner, Art Unit 2881